

**Notice of Allowability**

Application No.

10/735,487

Applicant(s)

BOTHE ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_.
2. ☒ The allowed claim(s) is/are 7-16.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date ____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date ____     | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|  | 9. <input type="checkbox"/> Other ____.  |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. William Valence on March 22, 2007.

The application has been amended as follows:

Claim 8 has been rewritten as follows: --

8. The  $11\beta$ -substituted steroids selected from the group consisting of
- 21-tert.butyl-17-hydroxy- $11\beta$ -(3-methoxyphenyl)-19-nor- $17\alpha$ -pregna-4, 9-dien-20-yn-3-one;
- methyl-4- {17-hydroxy- $11\beta$ -[3-(methoxy)phenyl] -3-keto-19-nor- $17\alpha$ -pregna-4, 9-dien-20-yn-21-yl))benzoate;
- 3-{17-hydroxy- $11\beta$ -[3-(methoxy)phenyl]-3-keto-19-nor- $17\alpha$ -pregna-4, 9-dien-20-yn-21-yl))-benzaldehyde;
- 4-{17-hydroxy- $11\beta$ -[3-(methoxy)phenyl]-3-keto-19-nor- $17\alpha$ -pregna-4, 9-dien-20-yn-21-yl))-phenylacetate;
- 17-hydroxy- $11\beta$ -[3-(methoxy)phenyl]-21-(4-pyrrolyl)phenyl-19-nor- $17\alpha$ -pregna-4, 9-dien-20-yn-3-one;
- 17-hydroxy-21-(4-hydroxyphenyl)- $11\beta$ -[3-(methoxy)phenyl]-19-nor- $17\alpha$ -pregna-4, 9-dien-20-yn-3-one;

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17-hydroxy-21-(4-mesyphenyl)-11 $\beta$ -(3-methoxyphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one;

21-tert.butyl-17-hydroxy-11 $\beta$ -(3-ethoxyphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one;

21-(4-tert.butylphenyl)-17-hydroxy-11 $\beta$ -(3-methoxyphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one;

ethyl(E)-3-[17-hydroxy-11 $\beta$ -(3-methoxyphenyl)-3-keto-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-21-yl))-isocrotonate;

21-(3,5-difluorophenyl)-17-hydroxy-11 $\beta$ -(3-methoxyphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one;

21-(2-trifluorophenyl)-17-hydroxy-11 $\beta$ -(3-methoxyphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one;

21-(3,5-dimethylphenyl)-17-hydroxy-11 $\beta$ -(3-methoxyphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one;

4-{17-hydroxy-11 $\beta$ -[3-(methoxy)phenyl]-3-keto-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-21-yl))-phenylsulfamate;

17-hydroxy-21 -(1-hydroxy-1-methylethyl)-11 $\beta$ -(3-methoxyphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one;

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3 -(17-hydroxy-3-keto-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-11 $\beta$ -yl)benzaldehyde, (E)-3-[17-hydroxy-11 $\beta$ -(3-methoxyphenyl)-3-keto-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-21-yl)]-benzaldoxime;

17-hydroxy-21-(1-methoxy-1-methylethyl)-11 $\beta$ -(3 -methoxyphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one;

17-hydroxy-21-(4-mesylylphenyl)-11 $\beta$ -(3 -methylphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one;

17-hydroxy-21-(4-mesyloxyphenyl)-11 $\beta$ -(3-methylphenyl)-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-3-one; and

4-{17-hydroxy-11 $\beta$ -[3-methylphenyl]-3-keto-19-nor-17 $\alpha$ -pregna-4, 9-dien-20-yn-21-yl}-phenylaminoacetate.

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Claim 10 has been rewritten as follows: --

10. The 11 $\beta$ -substituted steroids as defined in claim 7, wherein R<sub>1</sub> denotes said methoxy and R<sub>2</sub> denotes said substituted phenyl wherein said at least one substituent is said -CH=NOH, said pyrrolyl, said aminoacetate, said -CHO, said hydroxy, or said sulfamate.

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2. The following is an examiner's statement of reasons for allowance:

The rejections under 35 USC 103 have been withdrawn in light of applicant's amendment and argument filed January 16, 2007. The closest prior art, including those of record, does not provide sufficient guidance to enable the skilled artisan to arrive at the specific compounds of the instant invention. In addition, as argued by applicant, the claimed compounds have been shown to have significantly better dissociation, i.e., they bind satisfactorily to the glucocorticoid receptor and only slightly to progesterone receptors compared to the prior art compound, RU 38486.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


### ***Telephone Inquiry***

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
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BB

March 22, 2007